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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,215	01/03/2007	Kazuo Suzuki	2006_1634A	7223

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WENDEROTH, LIND & PONACK, L.L.P.
1030 15th Street, N.W.,
Suite 400 East
Washington, DC 20005-1503

EXAMINER	
DICKINSON, PAUL W	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
03/21/2012	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ddalecki@wenderoth.com
eoa@wenderoth.com

Office Action Summary	Application No.	Applicant(s)	
	10/594,215	SUZUKI ET AL.	
	Examiner	Art Unit	
	PAUL DICKINSON	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 February 2012*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1,2,5-7 and 36-45* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-2, 5-7 and 36-45* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/GB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/13/2012 has been entered.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objects are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

New Grounds of Rejection

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 45 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 45 recites "the oral hypoglycemic agent" of claim 41 or 42. As claim 41 and 42 do not disclose an oral hypoglycemic agent, there is insufficient antecedent basis for this term.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 5-7, and 8-45 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 2003011308 (WO '308; document already in record; US 20040191209 is an English equivalent). WO '308 discloses that administration of colestimide (a pharmaceutically acceptable anion exchange resin that has a bile acid-absorbing ability; a pharmaceutically acceptable anion exchange resin that is synthesized by a polymerization reaction of an epichlorohydrin derivative and an amine) inhibited blood sugar elevation after eating in patients with hypercholersterolemia complicated by type 2 diabetes (a symptom of type 2 diabetes) (examples). WO '308 also describes that similar effects were achieved when a sulfonylurea drug was used in combination (examples 1 and 4). The sulfonylurea drug (sulfonylurea agent; an oral hypoglycemic agent) may be administered simultaneously, separately, or sequentially (paragraph 9). Type 2 diabetes is a disease caused by insulin resistance as described

in paragraph 36 of the instant specification. The above method described by WO '308 is a method for improving insulin resistance (instant claims 1, 36, and 41). "Improving insulin resistance" is a broad term. Insulin resistance is a physiological condition where the natural hormone insulin becomes less effective at lowering blood sugars. Type 2 diabetes results from insulin resistance (see instant specification, paragraph 36). The reason blood glucose levels in diabetes patients elevates outside the normal range is because of insulin resistance. Thus inhibiting blood sugar elevation in type 2 diabetes patients is improving insulin resistance, as it is mitigating the effect of insulin resistance, that is, it is inhibiting elevation of blood glucose levels which would otherwise elevate because of insulin resistance in these patients. As the method of WO '308 inhibits elevation of blood glucose levels which would otherwise increase because of insulin resistance in these patients, it is a method of improving insulin resistance. Furthermore, the references meet every limitation of the claimed method in that the prior art method comprises administering orally to a diabetes patients (a patient in need of improving insulin resistance) colestimide as an active ingredient (an insulin resistance-improving agent comprising a pharmaceutically acceptable anion exchange resin as an active ingredient).Although WO '308 does not explicitly teach "selecting a patient in need of improvement of insulin resistance from patients suffering from... type 2 diabetes", selection of a patient is an implied step in the method of WO '308, as the drug will be administered to a patient in need of improvement of insulin resistance suffering from type 2 diabetes.

Claims 1, 6-7 and 36, 39-41, and 44-45 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5468727 ('727; document already in record). '727 teaches a method for the treatment of hyperinsulinemia (hyperinsulinism; a disease or symptom resulting from insulin resistance) comprising orally administering cholestyramine resin (a pharmaceutically acceptable anion exchange resin having bile acid adsorbing ability) as an active agent to a patient in need thereof (abstract; claims 1-2 and 7; Example 3). An oral hypoglycemic agent, such as chlorpropamide (a sulfonylurea agent), may be administered simultaneously (col 5, lines 10-13; col 4, lines 57-60). Although '727 does not explicitly teach "selecting a patient in need of improvement of insulin resistance from patients suffering from... hyperinsulinism", selection of a patient is an implied step in the method of '727, as the drug will be administered to a patient in need of improvement of insulin resistance suffering from hyperinsulinism.

Claims 1, 5, 36, 38, 41, and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0793960 (EP '960; document already in record). EP '960 teaches a method for the treatment of renal dysfunction (a disease or symptom resulting from insulin resistance) comprising orally administering colestimide or cholestyramine resin (pharmaceutically acceptable anion exchange resins having bile acid adsorbing ability) as an active ingredient to a patient in need thereof (abstract; page 4, lines 54-55; page 5, lines 13-14 and 23-27; claims 1-3 and 7-8). Although EP '960 does not explicitly teach "selecting a patient in need of improvement of insulin resistance from patients suffering from... renal dysfunction", selection of a patient is an implied step in the

method of EP '960, as the drug will be administered to a patient in need of improvement of insulin resistance suffering from renal dysfunction.

Claims 1, 36, and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 9841216 (WO '216; document already in record). WO '216 teaches a method for the treatment of fatty liver (a disease or symptom resulting from insulin resistance) comprising orally administering cholestyramine resin (pharmaceutically acceptable anion exchange resin having bile acid adsorbing ability) as an active ingredient to a patient in need thereof (abstract; page 3, lines 1-10; page 4, lines 2-17). Although WO '216 does not explicitly teach "selecting a patient in need of improvement of insulin resistance from patients suffering from... fatty liver", selection of a patient is an implied step in the method of WO '216, as the drug will be administered to a patient in need of improvement of insulin resistance suffering from fatty liver.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/PAUL DICKINSON/
Examiner, Art Unit 1618

March 14, 2012